

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

REMARKS

Entry of the amendment is respectfully requested.

Claims 1-32 were pending and have been rejected under § 103(a) over Kantner in view of Reidel, and further in view of Ganschow.

In response, claim 1 has been amended. New dependent claims 33-34 have been added. None of the amended, or newly added claims comprise new matter.

Favorable reconsideration of the claims is requested based on the remarks below and the amendments to the claims filed herewith.

Request of Withdrawal of Finality

Applicants respectfully request that the finality of the outstanding action be withdrawn in view of the fact that the Kantner reference has been applied in this case for the first time.

The previous amendment resulted from discussion between the undersigned and Examiner where Applicants merely incorporated Examiner's suggested terminology. This is the first opportunity that Applicants have had to respond to a rejection of this amended claim. As such, there has been no opportunity to define a

clear issue of disagreement. MPEP § 706.07. This is indicated by switching from one combination of references to another. *Id.*

In accordance with Patent Office guidelines, withdrawal of the outstanding rejection's finality is requested.

Rejection Under § 103(a)

Claim 1 has amended to specifically and narrowly define the claimed article as comprising an adhesive composition based on polystyrene block copolymers. Therefore, the claims recite a backing that is coated with a blend of (1) a hydrophobic polystyrene-copolymer based adhesive and (2) one or more pharmaceutically active components.

It is noteworthy that neither reference combines a hydrophobic adhesive with a pharmaceutically active agent. The major thrust of Kantner's teachings lie in the use of hydrophilic PEG-based adhesives. See Abstract; col 4, line 15 *et seq.* This composition is significantly different than that described in newly amended claim 1.

Further, Reidel does not cure the deficiency, because nowhere does Reidel disclose the desirability of using his specific tape's adhesive as a vehicle for delivering active agents. This lack of disclosure is likely based on two facts.

Reidel seeks a tape with "LAB" - low adhesion backside to improve release. Col 4, lines 3-14. Applicants seek a strong adhesion so that the active agent may have time to be released through the skin, with less chance of the backing coming off. See specification, p. 1, lines 24-26; p. 18, lines 3 *et seq.*

Another basis is that Reidel does not disclose the release properties of his adhesive. Kantner does indicate satisfactory release properties, but it is known that the release properties are likely to vary with the adhesive in which it is blended. Accordingly, based on Kantner's hydrophilic PEG-based adhesive, persons with skill in the art could not have reasonably predicted Applicants' hydrophobic polystyrene-adhesive-active agent composition.

Therefore, taken in combination, Kantner and Reidel's disclosures do not teach or suggest combining an active agent with Applicants hydrophobic polystyrene-based adhesive. Thus, a key claim limitation is not taught or suggested.

On this basis alone, the rejection over Kantner/Reidel should be withdrawn.

In addition, modifying Reidel's adhesive to apply to Kantner's tape or, *vice versa*, adding drug to Reidel's tape's adhesive for use as a delivery device, would render Reidel's tape unsuitable for its original use. This is because, whereas Reidel's purpose is to achieve a medical tape with LAB, Applicants seek exactly the opposite; the claimed composition of adhesive and drug is contemplated to maintain especially strong adhesive properties. Specification, top of page 18. Thus, the claimed combination of Kantner and Reidel do not render the claims obvious. MPEP § 2143.01 (*"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."* *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

CONCLUSION

Applicants suggest that neither Kantner nor Reidel in combination or individually, provide sufficient guidance to arrive that the invention of claim 1. Specifically, there is no teaching or suggestion as to how to vary the many experimental variables needed to achieve the proper balance for strong adhesion while maintaining the desired release properties.

Viewed in this light, Kantner and Reidel provide a nonenabling disclosure that rises, at best, to the level of *obvious to try*; i.e., they provide an invitation to experiment. However, this is insufficient to maintain the rejection because the combination of references fails to provide a reasonable expectation of success. See e.g., MPEP §§ 2143.02, 2144.06.

In view of these remarks and the foregoing amendments, withdrawal of the
rejections under § 103(a) is respectfully requested.

Respectfully submitted,
NORRIS, MCLAUGHLIN & MARCUS

A handwritten signature in dark ink, appearing to read 'Theodore A. Gottlieb', is written over a horizontal line.

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CLAIM AMENDMENTS

1. (Currently amended) A backing Backing-material for medical purposes, characterized in that the backing material is a nonwoven, overstitched by yarns, the backing material is coated partially or over its entire area on at least one side with an adhesive composition further comprising at least one pharmacologically active agent and wherein the adhesive composition comprises one or more polystyrene-block copolymers.
2. (Previously presented) The backing Backing-material for medical purposes, characterized in that the backing material is a nonwoven which is reinforced by the formation of stitches formed by loops from the fibers of the web, and the backing material is coated partially or over its entire area on at least one side with an adhesive composition further comprising at least one pharmacologically active agent.
3. (Previously presented) The backing Backing-material for medical purposes according to claim 1, characterized in that the number of stitches on the web comprises at least 3/cm.
4. (Previously presented) The backing Backing-material for medical purposes according to Claim 1, characterized in that the backing material generates a compression force of from 0.2 N/cm to 10 N/cm at an elongation of from 20% to 70%.
5. (Previously presented) The backing Backing-material for medical purposes according to claim 1, characterized in that the backing material has a basis weight of up to 500 g/m².
6. (Previously presented) The backing Backing-material for medical purposes according to Claim 1, characterized in that the backing material is reinforced with one or more monofil, multifil, staple fibre or spun fibre yarns and/or with oriented high-strength fibres, the yarns and/or fibres having in particular a strength of at least 40 cN/tex.

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7. (Previously present d) The backing ~~Backing~~-material for medical purposes according to Claim 1, characterized in that the backing material can be torn by hand perpendicular to the orientation of the stitches and/or in the direction of the stitches and/or perpendicular to the orientation of the reinforcement and/or in the direction of the reinforcement.
8. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition comprises a releasable active substance or substances in an amount of from 0.01 to 60% by weight.
9. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition is a hot-melt adhesive composition.
10. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition has a dynamic-complex glass transition temperature at a frequency of 0.1 rad/s of less than 15°C.
11. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition was foamed.
12. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition is applied partially to the backing material, especially by halftone printing, thermal screen printing, thermal flexographic printing or intaglio printing.
13. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition has been sprayed on.
14. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition is applied in the form of polygeometric domes to the backing material.

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15. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition is applied to the backing material with a weight per unit area of greater than 15 g/m².
16. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the adhesive composition can be sterilized, preferably with γ (gamma) radiation.
17. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that on the side opposite that coated with the self-adhesive composition, the backing material is finished with a water-repellent layer, impregnation, release layer and/or coating.
18. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that at least one additional layer comprising sheets, foams or nonwovens is applied on the backing material.
19. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the backing material is coated with metallic substances by vapour deposition.
20. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the coated backing material is covered after application of the self-adhesive composition or is provided with a wound pad or with padding.
21. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 1, characterized in that the number of longitudinal stitches on the web is at least 3/cm.
22. (Previously presented) The backing ~~Backing~~-material for medical purposes according to Claim 21, characterized in that the number of longitudinal stitches on the web is from 5 to 50/cm.

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23. (Previously presented) The backing ~~Backing~~-material for medical purposes according to Claim 5, characterized in that the backing material has a basis weight of from 10 to 350 g/m².
24. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 8, characterized in that the adhesive composition comprises a releasable active substance or substances in an amount of from 0.1 to 20% by weight.
25. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 10, characterized in that the adhesive composition has a dynamic-complex glass transition temperature at a frequency of 0.1 rad/s of less from 3°C to -30°C.
26. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 25, characterized in that the adhesive composition has a dynamic-complex glass transition temperature at a frequency of 0.1 rad/s of less from -3°C to -25°C.
27. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 15, characterized in that the adhesive composition is applied to the backing material with a weight per unit area of between 90 g/m² and 500 g/m².
28. (Previously presented) The backing ~~Backing~~-material for medical purposes according to claim 27, characterized in that the adhesive composition is applied to the backing material with a weight per unit area of between 130 g/m² and 500 g/m².
29. (Previously presented) The backing material of claim 1 wherein the at least one pharmacologically active agent comprises one or more pharmacologically active compounds.
30. (Previously presented) The backing material in claim 1 wherein the at least one pharmacologically active agent comprises one or more extracts of biological material.
31. (Previously presented) The backing material in claim 1 wherein at least a portion of the at least one pharmacologically active agent is not in co-mixture with the adhesive composition.

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32. (Previously presented) The backing material in claim 31 wherein the not co-mixed portion of the pharmacologically active agent is in one or more forms selected from the group consisting of particles, pellets, fibers or filaments, and regular- or irregular-shaped fragments.

33. (New) The backing material of claim 1, wherein the adhesive comprises between 10 wt.-% and 90 wt.-% of block copolymers.

34. (New) The backing material of claim 1, wherein the polystyrene block copolymer comprises units selected from the group consisting of ethylene, propylene, butylenes, butadiene, isoprene, or mixtures thereof.